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10/031,854	01/24/2002	Ashok Rajgarhia	145865.00013	8447

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,854	Applicant(s) Rajgarhia
	Examiner Christopher Tate	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Claims 1-4 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the following reasons:

- The phrase "synergistic composition ...characterized by" is indefinite because it is unclear if the composition consists of extracts from the two recited herbal plants or if the composition comprises these two extract ingredients. Accordingly, the ambiguous terminology "characterized by" causes any limitations recited thereafter to be unclear.
- The phrase "extract of Glycyrrhiza glabra and Picrorhiza kurroa" is indefinite because it is unclear if the singular term "extract" is defining only the first herbal or if it is defining both herbals - i.e., is the *Picrorhiza kurroa* plant also in the form of an extract or not?

Claims 2-4 are rendered indefinite by the phrase "characterized in that" and "characterized by". These phrases are ambiguous and, therefore, any limitations recited thereafter are unclear.

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Claim 3 is rendered vague and indefinite for the following reasons:

- The phrase "preparation of extract from roots of *Glycyrrhiza glabra* and *Picrorhiza kurroa*" is vague and indefinite for two reasons. Firstly, the metes and bounds of the phrase "preparation of extract" are not clearly nor adequately delineated - e.g., how is/are the extracts actually prepared? Secondly, it is unclear if "preparation of extract from the roots" is defining only the first herbal plant or both - , is the *Picrorhiza kurroa* plant also prepared in the form of an extract or not, and if so, is the extract thereof obtained from the roots?
- The phrase "optimization of the extract" (recited twice - once for each herbal extract) is exceedingly vague and indefinite - i.e., how and in what manner are each extract optimized so as "ensure the maximum content of" glycyrrhizin and kutkin, respectively? As such, the metes and bounds of this phrase with respect to ensuring the maximum content of" glycyrrhizin and kutkin are not clearly delineated nor adequately defined. Accordingly, claim 3 is deemed incomplete for omitting the essential steps necessary in preparing these essential optimized extracts containing glycyrrhizin and kutkin, respectively (see MPEP § 2172.01). It is strongly suggested that these two essential optimized herbal extracts be defined by defining the essential steps recited on page 4, lines 16-32, of the instant specification to overcome this rejection (it is also suggested claim 1 be expanded upon so as to recite a product-by-process which incorporates these essential steps).

Claim 4 is rendered vague and indefinite because it is unclear if the phrase "extract of *Picrorhiza kurroa*" (lines 2-3) is defining the extract from claim 3 or a different extract thereof. For clarity, it is suggest that the term --the-- be inserted before this phrase.

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Claim Rejections - 35 U.S.C. § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by Shah (US 5,693,327).

Although very unclear due to the U.S.C. 112, second paragraph rejections above, a composition comprising an extract of *Glycyrrhiza glabra* and an extract of *Picrorhiza kurroa* within the weight ratio range of 2-1:1-3 is apparently claimed.

Shah teaches an herbal composition comprising an extract of *Glycyrrhiza glabra* (also known as *Glycyrrhiza glabra*) and an extract of *Picrorhiza kurroa* (also known as *Picrorhiza kurroa*), including in a ratio of 1:1 (see, e.g., entire document including col 4, lines 39-55).

Therefore, the reference is deemed to anticipate the instant claim above.

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Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US 5,693,327).

Shah is relied upon for the reasons discussed *supra*. In addition, Shah teaches that the herbal compositions taught therein have numerous therapeutic uses including having anti-inflammatory activity (one of the disclosed activities of the instant herbal extract composition). Shah further teaches that it is well known in the art to utilize *Glycerhiza glabra* (also known as *Glycyrrhiza glabra*) in combination with *Picrorhiza curroa* (also known as *Picrorhiza kurroa*) - see, e.g., cols 9-10, Herbal #13 (which list *Picrorhiza curroa* under Potential Uses of *Glycerhiza glabra* and, thus, indicates their combinational use). It should also be noted that Applicant admittedly disclose that the two herbal extracts can be prepared in any known manner (see, e.g., page 4, lines 13-14 of the instant specification), which apparently indicates that any type of extracts from the recited herbals read upon optimized extracts thereof.

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As the Shah reference clearly indicates that the various proportions and amounts of the ingredients used within such herbal compositions are result effective variables, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by the reference. Accordingly, the result-effective adjustment of such conventional working conditions would have been obvious to one of ordinary skill in the art at the time the claimed invention was made (e.g., determining appropriate amounts of each herbal ingredient and/or optimized extraction steps) and is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

With regard to the U.S.C. 102 and 103 rejections above, it is noted that the reference does not expressly teach that the composition can be used in the manner instantly claimed (to treat liver and liver associated ailments), however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103 (MPEP 2112).

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Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramoniam et al. (Ind. J. Pharm., 1999), with evidence provided by Ram (Drug News and Perspective, 2001 - please note that this review article is only being cited as evidence of the well known long term tradition use of the two recited herbals as hepatoprotective agents prior to the effective filing date of the instant application, and not as prior art itself).

Subramoniam et al. teach that it is well known and common in the art to use polyherbal formulations containing extracts of *Glycyrrhiza glabra* and *Picrorhiza kurroa* as active ingredients for treating liver ailments, and that the use of a combination of different herbal extracts within such polyherbal formulations is desirable since they advantageously provide multiple therapeutic activities to the liver - such as the activities demonstrated by *Glycyrrhiza glabra* and *Picrorhiza kurroa* (see entire document including abstract, pages 168-171 and Figure 1). The result-effective adjustment of conventional working conditions (e.g., utilizing a conventional weight ratio of the two claimed herbal ingredients - e.g., using a 1:1 weight ratio or similar ratio of *Glycyrrhiza glabra* and *Picrorhiza kurroa* extract within such an hepatoprotective formulation; and/or determining optimized herbal extraction steps) would have been obvious to one of ordinary skill in the art at the time the claimed invention was made having the Subramoniam et al. reference before him/her (especially since each of these herbal extracts has been well known and recognized in the art for many years as being useful for the claimed purpose - i.e., for treating liver ailments such as hepatitis, as disclosed by Subramoniam et al.; and as evidenced by Ram with respect to the teachings therein concerning the traditional

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long term prior use of the two claimed herbal ingredients as hepatoprotective agents: see entire Ram article including abstract and pp 359-360 and the references cited therein concerning *Glycyrrhiza glabra* and *Picrorhiza kurroa* as hepatoprotective agents) and, thus, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

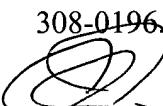
Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.


Christopher R. Tate
Primary Examiner, Group 1654